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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,145	08/22/2003	Bong Cheol Kim	DE-1501	8727

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
11/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,145	KIM ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *146-232* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *146-232* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The previous office action mailed on October 3, 2008 is herewith vacated.

The Office Action is in response to the Applicant's reply filed June 3, 2008 to the Office Action mailed on October 29, 2007.

Applicant's arguments over the 35 U.S.C. 112 first rejections of claims 38, 40-72 and 110-145 is persuasive in view of amendments made to the claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103(a) rejection of claims 38, 40-59, 62, 65-67, 110-112 over Murad (US 6,630,163), of record, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) is persuasive in part in view of cancellation of claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103(a) rejection of claims 38, 40-64, 69-72, 110-135, 137-139 and 142-145 over Forastiere et al. ("Consumption of fresh fruit rich in vitamin C and wheezing symptoms in children", Thorax 2000, 55: 283-288), cited by the Applicant, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A)is persuasive in part in view of cancellation of claims. Therefore, the rejection is herewith withdrawn.

The following new and modified rejections are now made addressing the new claims:

Claim Rejections - 35 USC § 11 2

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any : person skilled in the ad to which it pertains, or with which It is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 146, 149-176 and 204, 208-232 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for inhibition or reduction of IgE production in a mammal in need thereof, said method comprising administering an extract of kiwifruit of the genus Actinidia to said mammal, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApIs 1986) at 547 the court recited eight factors:

(1) the nature of the invention', (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims', (6) the amount of direction or guidance presented', (7) the presence or absence of working examples', and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1). The Nature of the Invention: All of the rejected claims are drawn to an invention which pertains to "a method for inhibiting or reducing IgE production and histamine release in a mammal in need thereof, said method comprising administering an extract of kiwifruit of the genus Actinidia to said mammal, wherein said extract is provided in an amount sufficient to inhibit or reduce IgE production histamine release in said mammal, and wherein said method treats, alleviates or reduces one or more symptoms of an allergic disease selected from the group consisting of: anaphylaxis, allergic rhinitis, allergic conjunctivitis, allergic dermatitis, atopic dermatitis, contagious dermatitis, urticaria, insect allergy, food allergy and drug allergy."

(2). The state of the prior art: In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of inhibit or reduce IgE production and histamine release in a mammal. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed inhibition or reduction of IgE production and histamine release in a mammal.

(3). The predictability or unpredictability of the art: the art does not enable a person of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. The burden of enabling one skilled in the art to inhibit or reduce IgE production and histamine release in a mammal. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of inhibiting or reducing IgE production and histamine release in a mammal. Nor is there any guidance provided as to a specific protocol to

be utilized in order to show the efficacy of the presently claimed inhibition or reduction of IgE production and histamine release in a mammal.

The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for inhibiting or reducing IgE production and histamine release in a mammal. The term "inhibit" or "inhibiting" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success. Since absolute success is not as of yet reasonably possible with most diseases/disorders, the specification is viewed as lacking an adequate enablement of inhibiting or reducing IgE production and histamine release in a mammal.

(4). The breadth of the claims: the claims encompass a method of inhibiting or reducing IgE production and histamine release in a mammal. Applicant fails to set forth the criteria that define the inhibition or reduction of IgE production and histamine release in a mammal.

(5). The amount of direction or guidance presented: does not provide any guidance in terms of inhibition or reduction of IgE production and histamine release in a mammal.

(6). The presence or absence of working examples: applicant does not provide any working examples for the inhibition or reduction of IgE production and histamine release in a mammal. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the inhibition effects of the instant composition.

(7). The quantity of experimentation necessary: the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples, "the level of skill in the art' and "predictability" etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, unpredictability of inhibition or reduction of IgE production and histamine release in a mammal, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 146-232 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US 6,630,163), of record, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and further in view of Wuthrich (Serum IgE in atopic dermatitis; Clinical & Experimental Allergy Volume 8 Issue 3, Pages 241 - 248), Lukacs et al. (US 20020006410 A1), and Capetola et al. (US4444780 A).

Murad teaches a method of treating dermatological disorders, including those of inflammatory nature such as inflammatory dermatoses, with fruit extracts, including kiwi fruit extract. See col. 8, lines 10-29. The fruit extract is present in an amount of 0.01-80 wt. %. See col. 8, lines 13-16. Murad teaches the same amounts of the extract.

Wuthrich is solely used to show that atopic dermatis is associated with an increase in IgE production.

Lukacs et al. is solely used to show that in treating inflammatory disease results in a decrease in the production of Th2-type antibody isotypes, such as IgG1 and IgE, and/or an increase in the production of Th1-type antibody isotypes, such as IgG2a or IgG3.

Capetola et al. is solely used to show the relationship between atopic dermatitis and histamine release and edema.

While broadly teaching "kiwi fruit", Murad does not explicitly teach the claimed species of kiwi fruit.

However, Endres et al. and Udagawa show that extracts of the claimed species of kiwi fruit are known in the art and used in cosmetics and pharmaceuticals. See respective Abstracts.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use Actinidia arguta, Actinidia kolomikta or Actinidia polygama of Endres et al. or Udagawa for compositions of Murad for their art-recognized purpose with a reasonable expectation of achieving the desired cosmetic results. Selection of a known material based on its suitability for its intended

use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Murad does not explicitly teach the kind of extract as claimed herein. However, Udagawa teaches crude extracts. See Abstract. The crude extract of kiwi fruit is soluble in both water and alcohol because it's a juice. With respect to Claims 159-167 and 188-196, these claims are in a product-by-process format and as such as not limited to the extracts produced by a recited method. A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim. See *Scripps Clinic & Research Foundation v. Genentech, Inc.* (CAFC 1991) 927 F2d 1565, 18 PQ2d 1001. Process limitations cannot impart patentability to a product which is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985) 771 F2d 695, 227 USPQ 964.

Claims 146-148, 150-177, 179-206,208-232 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forastiere et al. ("Consumption of fresh fruit rich in vitamin C and wheezing symptoms in children", Thorax 2000, 55: 283-288), cited by the Applicant, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and further in view of Lee et al. (Oral Administration of IL-12 Suppresses Anaphylactic Reactions in a Murine Model of Peanut Hypersensitivity Clinical Immunology Vol. 101, No. 2, November, pp. 220–228, 2001) and Wei (US 5177060 A).

Forastiere et al. teach consumption of kiwi fruit reduced the occurrence of asthmatic symptoms, which might be attributed to an anti-inflammatory action of vitamin C. See pp. 283, 285. Consuming kiwi fruit as a food meets the limitation "crude extract"

of the instant claims. Further, kiwi fruit is known to contain sugars. Furthermore, the kiwi fruit juice extracted during eating the fruit is liquid and is soluble in water and alcohol.

Lee et al. is solely used to show that allergic asthma is associated with histamine release, serum IgE. IgG1, IgG2, Th2, and Th1 levels.

Lee et al. is solely used to show the relationship between asthma and edema.

While broadly teaching "kiwi fruit", Forastiere et al. do not explicitly teach the claimed species of kiwi fruit. However, Endres et al. and Udagawa show that extracts of the claimed species of kiwi fruit are known in the art and used in cosmetics, food and pharmaceuticals. See respective Abstracts.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use Actinidia arguta, Actinidia kolomikta or Actinidia polygama of Endres et al. or Udagawa for method of Forastiere et al. with a reasonable expectation of achieving the desired therapeutic results. Selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). With respect to Claims 159-167 and 188-196, these claims are in a product-by-process format and as such as not limited to the extracts produced by a recited method. A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim. See *Scripps Clinic & Research Foundation v. Genentech, Inc.* (CAFC 1991) 927 F2d 1565, 18 PQ2d 1001. Process limitations cannot impart patentability to a product which is not patentably distinguished

over the prior art. *In re Thorpe et al.* (CAFC 1985) 771 F2d 695, 227 USPQ 964. Forastiere et al. do not explicitly teach the concentration of the extract. However, it is believed that if the entire fruit is a "composition", the fruit juice extracted during eating the fruit would constitute roughly from one third to half of the entire fruit, depending on its ripeness, and, therefore, meet the concentration limitations of the instant claims.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed June 3, 2008 have been fully considered. The response to the arguments is as discussed below:

Applicant argues there are no working examples showing the Murad compositions are used in treating inflammatory dermatoses. Examiner's contention is that Murad in fact teaches a method of treating dermatological disorders, including those of inflammatory nature such as inflammatory dermatoses, with fruit extracts, including kiwi fruit extract. See col. 8, lines 10-29. Further, the selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Applicant argues that Endres fails to teach allergic diseases. Examiner points to page 12 of Endres wherein the hardy kiwi juice is used in treating psoriasis an allergic inflammatory disease.

Applicant is informed that a prior art composition that comprise all elemental components of the instantly created composition would meet all functional characteristics of the created composition, because such characteristics are inseparable from the composition. Murad, Endres, Forastiere et al., and Udagawa meet all elemental steps of the instant claims and the compositions created thereof. Since Murad, Endres, Forastiere et al., and Udagawa compositions are prepared by the same steps as the instantly claimed process and further comprise all elemental components of the instantly prepared composition, they would obviously exhibit the same IgE, IgG1, IgG2a, Th1 cytokine, or Th2 cytokine serum level properties as those instantly claimed, because such functional characteristics of the created composition is inseparable from the describe composition of Murad, Endres, Forastiere et al., and Udagawa.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use Actinidia arguta, Actinidia kolomikta or Actinidia polygama of Endres et al. or Udagawa for method of Forastiere et al. with a reasonable expectation of achieving the desired therapeutic results. Selection of a known material based on its

suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

The arguments are not persuasive and the rejection is made **FINAL**.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617